UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,547	04/22/2004	James Esler	279.B44US1	7290

21186   7590   03/13/2009
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ART UNIT	PAPER NUMBER
4114	

MAIL DATE	DELIVERY MODE
03/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS,
WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2004*.
2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.
    4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-45* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on *22 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    a)☐ All   b)☐ Some * c)☐ None of:
       1.☐ Certified copies of the priority documents have been received.
       2.☐ Certified copies of the priority documents have been received in Application No. _____.
       3.☐ Copies of the certified copies of the priority documents have been received in this National Stage
          application from the International Bureau (PCT Rule 17.2(a)).
    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.
4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.
5)☐ Notice of Informal Patent Application
6)☐ Other: _____.

DETAILED ACTION

Status of Claims

1.   This action is in reply to application 10829547 filed on 04/22/2004.

2.   Claims 1-45 are currently pending and have been examined.

Claim Rejections - 35 USC § 112

3.   The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1.   Claims 6, 8-10 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with

the enablement requirement. These claims recite "install", "installing", "implanting", "uninstalling",

and "explanting" medical devices but the claims and specification do not provide any particular

structure or method by which to perform this procedure.

2.   The claims describe the desired result of this type of procedure. However, the claims themselves

do not define the structure or method of the function used to reach that result. The claimed

limitations do not fall under 35 USC § 112 ¶ 6 - "means for," which would allow the scope of the

claim to be defined as the particular methods or structure enumerated in the specification.

Further, one of ordinary skill in the art would not understand the "installing" or "uninstalling"

limitations to imply any particular structure or method. Therefore, the claim is properly construed

to encompass any and all means for installing and uninstalling.

3.   When a limitation encompasses any and all structures or acts for performing the recited function,

including those which were not what the applicant had invented, the disclosure fails to provide a

scope of enablement commensurate with the scope of the claim. See Ex parte Miyazaki, Appeal No. 2007-3300, p. 27 (BPAI, 2008) (referencing Halliburton Oil Well Cementing Co. v. Walker, 329 US 1 (1946)). Because the disclosure does not enable every structure and act that reasonably falls within the claim's scope, the disclosure fails to provide an adequate scope of enablement as required by 35 USC 112, first paragraph.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 18, 33, 37, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 1 recites the limitation "(OR wherein the DMA does not originate within the medical device)". This appears to be a phrase that was not cut during the final drafting of the claims. The term "the DMA" has insufficient antecedent basis for this limitation in the claim. Correction is required.

7. Claim 18 recites the limitation "the programmer" in line 6. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 33 recites the limitation "causing a computer to at least one of initialize and install the medical device" in lines 2 and 3. A computer does not have the ability to install a medical device, therefore this claim is indefinite.

9.   Claim 37 recites "any data format" in lines 2 and 3. This phrase does not make clear what type of format the applicant is referring to and is therefore indefinite.

10.   Claim 40 recites "means for inputting the data message alert" in lines 1 and 2. This means (or step) plus function limitation that invokes 35 U.S.C.112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. Examiner construed the means for to be a computer program for purposes of examination.

11.   Applicant is required to:

(a)   Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b)   Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

12.   If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a)   Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b)   Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

Claim Rejections - 35 USC § 101

13.　　　35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

14.　　　Claims 30-35 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 30-34 are directed towards a computer program product. A computer program product is described on page 4, lines 16-18 of the specification as being a signal. Signals are not considered part of any one of the four statutory categories of invention and are therefore not statutory. Claim 35 is directed towards a signal. Signals are not considered part of any one of the four statutory categories of invention and are therefore not statutory.

Claim Rejections - 35 USC § 103

15.　　　The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16.　　　The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1.　　　Determining the scope and contents of the prior art.
2.　　　Ascertaining the differences between the prior art and the claims at issue.
3.　　　Resolving the level of ordinary skill in the pertinent art.

4.   Considering objective evidence present in the application indicating obviousness or nonobviousness.

Examiner's Note: The Examiner has pointed out particular references contained in the prior art of record within the body of this action for the convenience of the Applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply. Applicant, in preparing the response, should consider fully the entire reference as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner.

17.   Claims 1-6, 8, 11-14, 16-20, 22, 23, and 25-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine, et al. (US 6,327,501 B1) in view of Linberg, et al (US 6,497,655 B1).

18.   **Claim 1:**

Levine, as shown, discloses the following limitation:

- *upon interrogating the medical device, communicating via the computing device, a data message alert stored within a memory of the medical device wherein the data message alert originates from outside the medical device. (OR wherein the DMA does not originate within the medical device)* (see at least column 7, lines 9-35, i.e. programmer receives safely alert message that is stored within the medical device that was from an external source)

Levine does not disclose the following limitation, but Linberg as shown does:

- *interrogating the medical device with a computing device* (see at least column 9, lines 31-44, i.e. programmer interrogates IMD);

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the technique of safety alerts for implantable medical devices of Levine with the ability to interrogate a medical device with a computing device of Linberg because it provides, "...a highly

flexible and adaptable communications scheme to promote continuous and real-time communications…" (Linberg, column 9, lines 32-34)

19.   **Claim 2:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *detecting whether the data message alert is stored within the memory of the medical device wherein the data message alert is communicated in response to detecting the data message alert stored within the memory of the medical device* (see at least column 7, lines 9-35, i.e. indicator is stored in memory of implantable medical device and is provided to subsequent medical practitioners who interrogate the device).

20.   **Claim 3:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *the data message alert is stored in a dedicated alert field within the memory of the medical device* (see at least column 8, lines 52-61, i.e. dedicated memory field in medical device is flagged when safety alert data is associated with it).

21.   **Claim 4:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine, as shown, discloses the following limitations:

- *receiving a new data message alert* (see at least column 11, lines 13-20, i.e. programmer acquires safety alert);

- *in response to receiving the new data message alert, saving the new data message alert to the memory as the data message alert* (see at least column 12, lines 9-24, i.e. safety alert is saved and flagged in memory of medical device).

22.   **Claim 5:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine, as shown, discloses the following limitations:

- *receiving a revised data message alert* (see at least column 11, lines 13-20, i.e. programmer acquires safety alert);

- *in response to receiving the revised data message alert, saving the revised data message alert to the memory as the data message alert* (see at least column 12, lines 9-24, i.e. safety alert is saved and flagged in memory of medical device).

23.   **Claim 6:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *at least one of initializing and installing the medical device* (see at least column 10, lines 36-55, i.e. medical practitioner implants and initiates the operation of the implantable medical device).

24.   **Claim 8:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *implanting the medical device in a patient* (see at least column 10, lines 36-55, i.e. medical practitioner implants medical device).

25.   **Claim 11:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Linberg discloses the limitation of *the memory of the medical device comprises a random access memory (RAM)* (see at least column 12, lines 21-51). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the technique of safety alerts for implantable medical devices of Levine with the medical device random access memory

of Linberg because it is, "…generally employed to store operating commands and data for controlling device operation and for later retrieval to diagnose device function or patient condition…" (Linberg, column 12, lines 49-51)

26.   **Claim 12:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine, as shown, discloses the following limitations:

- *requesting the data message alert* (see at least column 5, line 52 - column 6, line 11, i.e. updated safety alert information can be requested by programmer via communication link);

- *in response to requesting the data message alert, interrogating the medical device* (see at least column 3, lines 3-31, i.e. programmer interrogates implanted medical device).

27.   **Claim 13:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine, as shown, discloses the following limitations:

- *establishing communication with the medical device* (see at least column 5, lines 19-27 and column 6, lines 44-55, i.e. programmer communicates with medical device by telemetry or other communications link);

- *reading the dedicated alert field* (see at least column 8, lines 13-24, i.e. programmer reads dedicated fields).

28.   **Claim 14:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Linberg discloses the limitation of *in response to detecting the data message alert stored, uploading the data message alert to a database* (see at least column 9, lines 45-61, i.e. review of status of components of IMD is performed and any problems are mined from IMD and uploaded to programmer's database). It would have been obvious to one of ordinary skill in the

art at the time of the invention to combine the technique of safety alerts for implantable medical devices of Levine with the data uploading practice of Linberg because it, "…provides significant advantages over the prior art by enabling remote troubleshooting, maintenance, and software upgrade to the IMDs…" (Linberg, column 9, lines 45-47)

29.   **Claim 16:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *at least one of the data message alert and the variety of data formats compatible for storage in the memory include at least one of the following data formats: ASCII text; multi-media; audio; audio encoding schema; XML; and XML schema definition* (see at least column 9, lines 5-42, i.e. safety alert data can be stored as text).

30.   **Claim 17:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *communicating the data message alert comprises at least one of the following: displaying a text pop-up window containing a text message alert via a display device of the computing device; displaying and playing a pop-up multi-media message alert via the display device and an audio output device of the computing device; playing an audio message alert via the audio output device of the computing device; and displaying a text pop-up window containing an XML text string message alert via the display device of the computing device* (see at least column 9, lines 22-42, i.e. safety alert information is displayed through the control unit of the external programmer as a text summary and may also include colors and flashing).

31.   **Claim 18:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *receiving a new data message alert comprises at*

least one of the following: receiving text of the new data message alert via a first input device of the computing device; receiving a multi-media recording of the new data message alert via a second input device of the programmer; receiving an audio recording of the new data message alert via one of the second input device and a third input device of the computing device; and receiving an XML text string of the new data message alert via one of the first input device and the second input device of the computing device (see at least column 11, lines 13-38, i.e. new safety alert information is received by diskette, from web sites, or by manual input).

32.   **Claim 19:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *detecting whether a data message alert is stored in the memory comprises detecting whether the dedicated alert field is null* (see at least column 13, lines 16-24 and figure 4, i.e. programmer searches for a safety alert data match in a particular dedicated field and if data match is not found in that dedicated field programmer moves to next dedicated field to detect data).

33.   **Claim 20:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Linberg, as shown, discloses the following limitations:

- *receiving an acknowledgement of the data message alert communicated* (see at least column 16, line 29 – column 17, line 25, i.e. IMD communicates an alert to chronic monitoring module (CMM) regarding a prevailing medical condition and CMM acknowledges receipt of alert by evaluating the need for the alert);

- *in response to receiving the acknowledgement, terminating communication of the data message alert* (see at least column 16, line 29 – column 17, line 25, i.e. IMD terminates session with CMM once CMM evaluates what type of medical condition alert is being sent).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the technique of safety alerts for implantable medical devices of Levine with the acknowledgement and termination of communication procedure of Linberg because it, "…provides significant advantages over the prior art by enabling remote troubleshooting, maintenance, and software upgrade to the IMDs…" (Linberg, column 9, lines 45-47)

34.   **Claim 22:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *the data message alert comprises at least one of patient-specific information and medical device-specific information* (see at least column 3, lines 32-48, i.e. safety alert information can pertain to components of medical device or complications experienced by the patient).

35.   **Claim 23:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *wherein the data message alert comprises at least one of the following: a message communicating that at least one of the medical device and a patient utilizing the medical device are enrolled in a clinical study; a message communicating a drug regime for the patient utilizing the medical device; a message communicating information concerning a component of the medical device; and a message communicating a reminder to send in a product registration for the medical device* (see at least column 3, lines 32-58, i.e. communicated safety alert message consists of information about medical device components).

36.   **Claim 25:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *in response to detecting that the dedicated alert field is not null, including the data message alert in any reports generated by the programmer*

(see at least column 13, line 63 - column 14, line 16, i.e. programmer can notify medical practitioner of safety alert information by generating a report on the display or through a printout). Levine does not explicitly disclose the limitation of *until the dedicated alert field is rendered null.* However, it is recognized in the art to clear data from a data field and render the data field empty. Therefore, it would have been obvious to one of ordinary skill in the art to combine the technique of safety alerts for implantable medical devices of Levin/Linberg with the ability to clear data from data fields. The reason to combine implantable medical device safety alerts with the ability to clear data from memory would be so memory space is cleared when the next alert data needs to be saved. This combination provides a predictable result since it is well known to clear data from memory on implantable medical devices because they have such limited memories and clearing the alert data would make room for the saving of future alert data.

37.   **Claim 26:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *the data message alert comprises a text message alert* (see at least column 9, lines 22-42, i.e. safety alert is displayed as a text summary) *and wherein including the data message alert in the any reports generated by the programmer comprises printing the text message alert in any printouts generated by the programmer* (see at least column 13, line 63 - column 14, line 16, i.e. programmer prints out safety alert information).

38.   **Claim 27:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine fails to explicitly disclose the limitation of *the text message alert is printed as header text of the any printouts generated by the programmer.* In at least column 14, lines 3-8, Levine discloses that the safety alert text is printed out from the programmer. Levine does not disclose that the text is printed as header text on any printouts. However, it is recognized in the art to print important alert text as a header on printouts. Therefore, it would have been obvious to

one of ordinary skill in the art at the time of invention to combine the ability to printout alert text from the programmer of Levine with the capacity to print that alert text as a header. The reason to combine the ability to printout alert text from the programmer with the capacity to print that alert text as a header would be to have the alert text stand out even more to the medical practitioner. This combination provides a predictable result because it is well known to printout important alert text as a header so that someone scanning through printouts can recognize it more quickly and readily.

39.   **Claim 28:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Linberg, as shown, discloses the following limitations:

- *interrogating the medical device with at least one wireless device in response to the medical device being within a communications range of the at least one wireless device* (see at least column 11, lines 13-22, i.e. a programmer placed a few feet away from IMD and patient would still be within range to wirelessly communicate with IMD);

- *upon interrogating the medical device with the wireless device, uploading the data message alert to a remote storage location via the wireless device* (see at least column 11, lines 13-35, i.e. data is communicated wirelessly to programmer from IMD and then programmer uploads data to data center).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the technique of safety alerts for implantable medical devices of Levine with the wireless communication and data storage system of Linberg because it, "...is designed to be broadband capable of simultaneously supporting multiple information sets and architecture, transmitting at relatively high speed, to provide data, sound and video services on demand..." (Linberg, column 12, lines 16-20)

40.   **Claim 29:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Linberg discloses the limitation of *interrogating the medical device with the wireless device comprises periodically establishing communication with the medical device and reading at least a portion of the memory* (see at least column 12, line 21 – column 13, line 15, i.e. programmer periodically reads memory of IMD wirelessly when it is a few meters away) *and wherein uploading the data message alert comprises transmitting the data message alert over a network to at least one of a remote database and the computing device* (see at least column 11, lines 13-35, i.e. data is communicated wirelessly to programmer from IMD and then programmer uploads data to data center). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the technique of safety alerts for implantable medical devices of Levine with the wireless communication and data storage system of Linberg because it, "...is designed to be broadband capable of simultaneously supporting multiple information sets and architecture, transmitting at relatively high speed, to provide data, sound and video services on demand..." (Linberg, column 12, lines 16-20).

41.   **Claim 30:**

Levine, as shown, discloses the following limitation:

- *upon interrogating the medical device, communicate a data message alert stored in a memory of the medical device wherein the data message alert originates from outside the medical device* (see at least column 7, lines 9-35, i.e. programmer receives safely alert message that is stored within the medical device that was from an external source).

Levine does not disclose the following limitation, but Linberg as shown does:

- *interrogate the medical device* (see at least column 9, lines 31-44, i.e. programmer interrogates IMD)*;*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the technique of safety alerts for implantable medical devices of Levine with the ability to interrogate a medical device with a computing device of Linberg because it provides, "...a highly flexible and adaptable communications scheme to promote continuous and real-time communications..." (Linberg, column 9, lines 32-34)

42.   **Claim 31:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *computer readable program code for causing the computer to detect whether the data message alert is stored in a dedicated alert field within the memory of the medical device wherein the data message alert is communicated in response to detecting the data message alert stored in the dedicated alert field* (see at least column 12, lines 9-24, i.e. programmer detects alert information corresponding to dedicated field and extracts that information from implantable medical device).

43.   **Claim 32:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine, as shown, discloses the following limitations:

- *receive the data message alert* (see at least column 7, lines 9-35, i.e. programmer receives safety alert messages);

- *in response to receiving the data message alert, save the data message alert to the dedicated alert field of the medical device* (see at least column 7, lines 9-35, i.e. programmer can store safety alert messages in memory of implantable medical device).

44.   **Claim 33:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *computer readable code for causing the computer*

to at least one of initialize and install the medical device prior to interrogating the medical device (see at least column 10, lines 36-55, i.e. medical device is implanted by medical practitioner and initiated by control program of programmer). Levine does not explicitly disclose the limitation of *the computer readable code for initializing the medical device includes computer readable code for causing the computer to clear the memory of any data message alerts.* However, it is recognized in the art to clear data from a data field and render the data field empty. Therefore, it would have been obvious to one of ordinary skill in the art to combine the technique of safety alerts for implantable medical devices of Levin/Linberg with the ability to clear data from data fields. The reason to combine implantable medical device safety alerts with the ability to clear data from memory would be so memory space is cleared when the next alert data needs to be saved. This combination provides a predictable result since it is well known to clear data from memory on implantable medical devices because they have such limited memories and clearing the alert data would make room for the saving of future alert data.

45.   **Claim 34:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *the computer readable code for causing the computer to communicate the data message alert includes computer readable code for causing the computer to communicate the data message alert in at least one of a variety of data formats compatible for storage in the memory wherein at least one of the data message alert and the variety of data formats compatible for storage in the memory include at least one of the following data formats: ASCII text; multi-media; audio; audio encoding schema; XML; and XML schema definition* (see at least column 9, lines 5-42, i.e. safety alert data can be stored as text).

46.   **Claim 35:**

Levine, as shown, discloses the following limitations:

- *receiving a data message alert via a programmer* (see at least column 7, lines 9-35, i.e. programmer receives safety alert messages);

- *in response to receiving the data message alert, saving the data message alert to a memory of the medical device* (see at least column 7, lines 9-35, i.e. programmer can store safety alert messages in memory of implantable medical device);

- *upon interrogating the medical device, communicating the data message alert via the programmer wherein the data message alert originates from outside the medical device* (see at least column 7, lines 9-35, i.e. programmer receives safely alert message that is stored within the medical device that was from an external source).

Levine does not disclose the following limitation, but Linberg as shown does:

- *interrogating the medical device* (see at least column 9, lines 31-44, i.e. programmer interrogates IMD);

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the technique of safety alerts for implantable medical devices of Levine with the ability to interrogate a medical device with a computing device of Linberg because it provides, "…a highly flexible and adaptable communications scheme to promote continuous and real-time communications…" (Linberg, column 9, lines 32-34)

47.   **Claim 36:**

Levine, as shown, discloses the following limitations:

- *a programmer, a medical device, a link between the programmer and the medical device* (see at least column 3, lines 3-31);

- *the programmer operative to provide and communicate a data message alert stored on the medical device* (see at least column 7, lines 9-35, i.e. safety alert messages are communicated to and from programmer);

- *the medical device storing the data message alert in a memory of the medical device* (see at least column 7, lines 9-35, i.e. safety alert messages are stored in memory of implantable medical device);

- *upon interrogating the medical device, communicate the data message alert wherein the data message alert originates from outside the medical device* (see at least column 7, lines 9-35, i.e. programmer receives safely alert message that is stored within the medical device that was from an external source).

Levine does not disclose the following limitation, but Linberg as shown does:

- *the programmer operative to interrogate the medical device* (see at least column 9, lines 31-44, i.e. programmer interrogates IMD);

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the technique of safety alerts for implantable medical devices of Levine with the ability to interrogate a medical device with a computing device of Linberg because it provides, "…a highly flexible and adaptable communications scheme to promote continuous and real-time communications…" (Linberg, column 9, lines 32-34)

48.   **Claim 37:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *the memory includes a free form data field having the capability to store the data message alert in any data format* (see at least column 5, lines 3-27, i.e. medical device can store analog and digital data) *and wherein the programmer is further operative to communicate the data message alert in any data format in which the data message alert is stored* (see at least column 9, lines 5-42, i.e. programmer memory stores and communicates safety alert data in any format available including text).

49.   **Claim 38:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *the free form data field comprises a dedicated alert field* (see at least column 7, line 62 – column 8, line 38, i.e. dedicated fields are included in medical device memory) *and wherein the programmer is further operative to detect whether the data message alert is stored in the dedicated alert field* (see at least column 8, lines 52-61, i.e. dedicated memory field in medical device is flagged when safety alert data is associated with it) *and in response to detecting the data message alert stored, communicate the data message alert* (see at least column 9, lines 43-55, patient complication alert recognized in memory is communicated to medical practitioner).

50.   **Claim 39:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *the link between the programmer and the medical device comprises a radio frequency (RF) signal* (see at least column 6, lines 44-55).

51.   **Claim 40:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *the programmer includes means for inputting the data message alert and wherein the programmer is further operative to: receive the data message alert prior to detecting the data message alert stored; and in response to receiving the data message alert, save the data message alert to the dedicated alert field* (see at least column 7, lines 9-35).

52. **Claim 41:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *the programmer includes at least one of a display, a printer, and an audio output device* (see at least column 6, lines 12-43, i.e. programmer includes graphical display unit and printer) *and wherein upon interrogating the medical device, the programmer communicates the data message alert as at least one of the following: a pop-up window containing an ASCII text message displayed on the display; a pop-up window containing a multi-media message displayed on the display and played via the audio output device; an audio message played via the audio output device; a pop-up window containing an XML text string message displayed on the display; and a printed text message printed as a header on any printout generated by the programmer until the data message alert is no longer stored in the memory of the medical device* (see at least column 9, lines 22-42, i.e. safety alert information is displayed through the control unit of the external programmer as a text summary and may also include colors and flashing).

53. **Claim 42:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *the programmer is further operative to persistently communicate the data message alert until the data message alert is acknowledged* (see at least column 13, line 63 – column 14, line 16, i.e. once safety alert information is recognized by programmer it notifies medical practitioner by message on display or printout and insures medical practitioner is aware of the safety alert information).

54. **Claim 43:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine, as shown, discloses the following limitations:

- *upload at least one of the data message alert, associated patient data, and associated medical device data to the database in response to communicating the data message alert stored in the memory* (see at least column 3, lines 3-31);

- *in response to uploading, provide verification that at least one of the data message alert, the associated patient data, and the associated medical device data is uploaded to an associated storage location within the database* (see at least column 5, line 52 - column 6, line 31, i.e. programmer is connected to separate database which is used to store safety alert information and this is verified during communications with implanted medical device).

55.   **Claim 44:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Linberg, as shown, discloses the following limitations:

- *interrogate the medical device in response to the medical device being within a communications range of the wireless device therein detecting whether the data message alert is stored in the memory* (see at least column 11, lines 13-22, i.e. a programmer placed a few feet away from IMD and patient would still be within range to wirelessly communicate with IMD and detect data in IMD memory);

- *in response to detecting the data message alert stored in the memory, upload at least one of the data message alert, associated patient data, and associated medical device data to the database* (see at least column 11, lines 13-35, i.e. data is communicated wirelessly to programmer from IMD and then programmer uploads data to data center).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the technique of safety alerts for implantable medical devices of Levine with the wireless communication and data storage system of Linberg because it, "...is designed to be broadband capable of simultaneously supporting multiple information sets and architecture, transmitting at relatively high speed, to provide data, sound and video services on demand..." (Linberg, column 12, lines 16-20)

56.   **Claim 45:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Linberg, as shown, discloses the following limitations:

- *interrogate the medical device in response to the medical device being within a communications range of the wireless device* (see at least column 11, lines 13-22, i.e. a programmer placed a few feet away from IMD and patient would still be within range to wirelessly communicate with IMD);

- *upon interrogating the medical device, upload the data message alert to the programmer via the networked link* (see at least column 11, lines 13-35, i.e. data is communicated wirelessly to programmer from IMD).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the technique of safety alerts for implantable medical devices of Levine with the wireless communication and data storage system of Linberg because it, "...is designed to be broadband capable of simultaneously supporting multiple information sets and architecture, transmitting at relatively high speed, to provide data, sound and video services on demand..." (Linberg, column 12, lines 16-20)

57.   Claim 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine, et al. (US 6,327,501 B1) in view of Linberg, et al (US 6,497,655 B1) in further view of Mann, et al. (US 5,833,623 A).

58.   **Claim 7:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Levine, as shown, discloses the following limitation:

- *entering a new data message alert* (see at least column 12, lines 9-24, i.e. safety alert is saved and flagged in memory of medical device).

The combination of Levine/Linberg does not disclose the following limitation, but Mann as shown does:

- *clearing the memory of any data message alerts* (see at least column 8, lines 31-44, i.e. medical device memory is cleared of data records);

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the technique of safety alerts for implantable medical devices of Levine/Linberg with the ability to clear the memory of a medical device of Mann because it, "...permits the subsequent capture of new diagnostic data..." (Mann, column 8, lines 35-36)

59.   Claims 9, 10, 15, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine, et al. (US 6,327,501 B1) in view of Linberg, et al (US 6,497,655 B1) in further view of Official Notice.

60.   **Claim 9:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. The combination of Levine/Linberg fails to explicitly disclose *uninstalling the medical device; and in response to uninstalling the medical device, interrogating the medical device.* However, the examiner takes Official Notice that it is old and well known in the art to uninstall medical devices and interrogate those medical devices once they are uninstalled. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the technique of safety alerts for implantable medical devices of Levine/Linberg with the ability to uninstall medical devices and interrogate those medical devices once they are uninstalled. The reason to combine implantable medical device safety alerts with the ability to uninstall medical devices and interrogate them once uninstalled would be to determine if any alerts are still in the memory of an uninstalled medical device. This combination provides a predictable result because it is well known to uninstall implantable medical devices because they have safety alerts for problems

such as improper battery consumption, corrosive damage, and mechanical wear that cause them to have to be replaced.

61.   **Claim 10:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. The combination of Levine/Linberg fails to explicitly disclose *uninstalling the medical device comprises explanting the medical device from the patient.* However, the examiner takes Official Notice that it is old and well known in the art to uninstall implantable medical devices by explanting them. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the technique of safety alerts for implantable medical devices of Levine/Linberg with the ability to uninstall implantable medical devices. The reason to combine implantable medical device safety alerts with the ability to uninstall implantable medical devices would be to have the ability to uninstall defective medical devices that are implanted in patients and have issued an alert that they are defective. This combination provides a predictable result because it is well known to uninstall implantable medical devices because they have safety alerts for problems such as improper battery consumption, corrosive damage, and mechanical wear that cause them to have to be replaced.

62.   **Claim 15:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. The combination of Levine/Linberg fails to explicitly disclose *communicating the data message alert in at least one of a variety of data formats compatible for storage in the memory.* However, the examiner takes Official Notice that it is old and well known in the art to communicate data in a variety of formats to store in a memory. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the technique of safety alerts for implantable medical devices of Levin/Linberg with the ability to communicate data in a variety of formats to a memory device. The reason to combine implantable medical device safety alerts with the

capability to transfer data in a variety of formats would be to have the ability to choose the way these safety alerts are communicated to different medical personnel. This combination provides a predictable result since it is well known to communicate data in various formats because different medical personnel may need to receive alert messages as texts, audio alerts, etc depending on the equipment they are using to receive these alerts.

63.   **Claim 21:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. The combination of Levine/Linberg fails to explicitly disclose *receiving a request to clear the data message alert from the dedicated alert field; and in response to receiving the request to clear, clearing the data message alert from the dedicated alert field whereby the dedicated alert field is rendered null.* However, the examiner takes Official Notice that it is old and well known in the art to clear data from a data field and render the data field empty. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the technique of safety alerts for implantable medical devices of Levin/Linberg with the ability to clear data from data fields. The reason to combine implantable medical device safety alerts with the ability to clear data from memory would be so memory space is cleared when the next alert data needs to be saved. This combination provides a predictable result since it is well known to clear data from memory on implantable medical devices because they have such limited memories and clearing the alert data would make room for the saving of future alert data.

64.   Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levine, et al. (US 6,327,501 B1) in view of Linberg, et al (US 6,497,655 B1) in further view of Haller, et al. (US 7,181,505 B2).

65.   **Claim 24:**

The combination of Levine/Linberg discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *uploading at least one of patient data and medical device data to the database* (see at least column 3, lines 3-31, i.e. programmer uploads medical device data and/or patient complication data to its memory). Levine does not explicitly disclose the limitations of *the message communicating that at least one of the medical device and the patient utilizing the medical device are enrolled in the clinical study and wherein the method further comprises: utilizing the data message alert to verify that at least one of the patient data and the medical device data are being uploaded to a correct study registry in the database for the clinical study.* However, it is recognized in the art to have a medical device communicate that the device or the patient using the device is enrolled in a clinical study and to have this data loaded into the correct clinical study database. For instance, in at least column 38, lines 38-61, Haller discloses that an IMD is interrogated by clinical studies for device and patient data to complete those clinical studies. Therefore, it would have been obvious to one of ordinary skill in the art to combine the technique of safety alerts for implantable medical devices of Levine with the ability to have clinical studies obtain patient and device data from medical devices in use. The reason to combine medical device alert signals with the ability of the device to communicate with clinical study databases is to reduce clinical study and overall healthcare costs. Additionally this increases the rate at which such studies may be completed, and the scope, amount and types of clinical data which may be acquired. This combination provides a predictable result because it is well known for medical devices to be involved in clinical studies for the gathering of data.

Conclusion

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **JOSEPH BURGESS** whose telephone number is **(571)270-5547.** The Examiner can normally be reached on

Monday-Friday, 9:00am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **JAMES REAGAN** can be reached at **(571)272-6710**.

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02/27/2009

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